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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/777,825

02/11/2004

Mark E. Cook

960296.00097

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27114

7590

10/06/2008

QUARLES & BRADY LLP

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EXAMINER

GUPTA, ANISH

ART UNIT

PAPER NUMBER

1654

NOTIFICATION DATE

DELIVERY MODE

10/06/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pat-dept@quarles.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/777,825	<b>Applicant(s)</b> COOK ET AL.	
	<b>Examiner</b> ANISH GUPTA	<b>Art Unit</b> 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 24-28 and 32-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24-28 and 32-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on 3-26-08 has been entered.

2. Applicants amendment, filed 3-26-08, is acknowledged. Claims 24 and 35 were amended and claims 2-7, 12-14, 16-20, and 29-31 were canceled. Claims 24-28 and 32-35 are pending in this application. Applicant's election with traverse of Group I, in the reply filed on 11-8-06 is acknowledged.

### **Withdrawn rejections**

3. The rejection of claims 2-3, 5-7, 14-17 and 21-23 rejected under 35 U.S.C. 102(b) as being anticipated by Draber et al. (J. Of Immunoglogical methods).

4. The rejection of claims 24-26, 29-35 rejected under 35 U.S.C. 103(a) as being unpatentable over Peebles et al. (US2950204).

5. The rejection of claims 2-3, 5-8, 12-14, 16-20 rejected under 35 U.S.C. 102(b) as being anticipated by Peebles et al. (US2950204).

6. Claims 24-26 and 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al. (US6213930) in view of Draber et al. and Andya et al.

***Claim Rejections - 35 USC § 103***

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 24-28 and 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al. (US6213930) in view of Draber et al. and Andya et al. and Freeman (US6746698).

The claims are drawn to a method for heat stabilizing a specific binding activity of a protein by subjecting the protein to a saccharide.

The reference of Cook et al. the use of anti-phospholipids A2 antibodies to enhance growth or improve animal feed (see abstract). The reference states a producer animal is immunized with a peptide or protein, such as PLA.sub.2, against which antibodies are desired so that the producer animal produces an antibody to said peptide or protein. A substance containing the antibody is obtained from said producer animal. The antibody can be subject to further purification if desired or can be used without further preparation in an animal feed (see col. 3, lines 63-67). Further, An egg preparation, e.g., egg yolks or whole eggs, containing the anti-PLA.sub.2 antibody can be

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collected and homogenized to form an emulsion. Thereby meeting the imitation of claim 7-12. The resulting emulsion can be dried to form a powder containing the anti-PLA2 antibody. This powder can then be formulated in a manner appropriate to the administration route and then administered to the desired animals using methods known in the art. The preparation is preferably administered orally, most preferably as a supplement to the animal's diet. (see col. 4, lines 14-22). The difference between the prior art and the instant application is that the reference does not teach the use of trehalose and does not teach a processing step at a temperature of at least 70°C.

However, Draber et al. teach the stabilization of antibodies using trehalose. The reference specifically teaches a method where the ascetic fluids or purified mAbs were freeze dreid in the presence of trehalose (see page 38). Trehalose provides effective stabilization during freeze-drying of IgM and such preparations can be stored at elevated temperatures (see page 41). The trehalose freeze dried preparation of IgG and IgM were found to be more stable (see page 41). Trehalose confers unique thermostability to biomolecules including liposome-hemoglobin, air-dried antibodies (see page 41). The reference of Andya et al. teach that anti-IgE monoclonal antibody during spray drying resulted in a stabilized antibody product and a in decrease rates of aggregation when trehalose was utilized (see page 355).

Furthermore, formation of tablets or pellets for animal feed are well known in the art. Freeman teaches generally speaking, the animal feed is prepared by combining the ingredients of the animal feed to form a mixture, and forming discrete plural particles of the animal feed from the mixture. Most preferably, the particles are formed by pelletizing the mixture. Those skilled in the art of pelletizing will appreciate that various conditions may be employed during the pelletizing process. Generally speaking, moisture levels in the pellet mill may range from about 5% to about 12%, with a product temperature ranging from about 120.degree F. to about 250.degree. F. (see col.

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4, lines 13-25). Pelleting allows for controlling amount of feed to different size animals by altering the size of the pellet.

Therefore, it would have been obvious to one of ordinary skill in the art to use trehalose with anti-PLA.sub.2 antibody because trehalose confers thermostability to dried formulations. It would have been further obvious to form pellets for feeding different size animals using conventional methods as taught in Freeman. Furthermore, during pelleting trehalose would confer thermostability to the animal feed mixture taught by Cook et al.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can normally be reached on (571) 272-0562. The fax phone number of this group is (571)-273-8300.

/Anish Gupta/  
Primary Examiner, Art Unit 1654